UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,159	03/31/2004	Jay A. Nadel	UCSF-085CON5	9049

24353 7590 03/06/2007

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER	
ZARA, JANE J	
ART UNIT	**PAPER NUMBER**
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,159	NADEL ET AL.	
	Examiner	Art Unit	
	Jane Zara	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the communication filed 12-4-06.

Claims 26-36 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group I, claims 2, 3, and 12-17 in the reply filed on 12-4-06 is acknowledged. The traversal is on the ground(s) that no undue burden would exist to examine all of the inventions claimed. This is not found persuasive because the different inventions encompass very distinct compositions and methods, and the searches required for proper examination of all of the inventions claimed would not be coextensive, although they might overlap. For instance, examination of the compositions and methods of Group III, drawn to antagonists that inhibit or mediate release of a transmembrane EGF-R ligand would be structurally, biologically, chemically and functionally distinct from Group IV, drawn to kinase inhibitors, or Group V, drawn to anti-oxidants.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-25 have been canceled and have been replaced with claims 27-36. Claims 26-36 have been examined as the elected invention as set forth in the Office below. Applicant timely traversed the restriction (election) requirement in the reply filed on 12-4-06.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn to compositions and methods fro treating nasal polyps comprising the administration of any epidermal growth factor receptor (EGF-R) antagonist. The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the very broad genus comprising EGF-R antagonists, and which provide for the function claimed, of treating nasal polyps in a subject. The specification and claims do not describe elements which are essential to the genus comprising such antagonists. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between members of the genus is permitted. Concise structural features that could distinguish structures or compounds within this genus from others are missing from the instant disclosure. The specification fails to teach or adequately describe a representative number of species in this broad genus such that

the common attributes or characteristics concisely identifying members of the genus are exemplified, and, because the claimed genus is so highly variant, the description provided is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus claimed. Thus, Applicant was not in possession of the claimed genus.

Claims 26-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing goblet cell hyperplasia in an airway of an individual comprising the administration of the EGF-R antagonist BIBX1522 prior to induction of EGF-R, does not reasonably provide enablement for methods of treating nasal polyps comprising the administration of any EGF-R antagonist via any mode of administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to methods of treating nasal polyps comprising the administration of any epidermal growth factor receptor (EGF-R) antagonist to a patient suffering from nasal polyps.

The nature of the invention. The claims are drawn to methods of treating nasal polyps in an individual comprising the administration of any antagonist to EGF-R. EGF-R antagonists encompass a wide range of compounds, including heterocyclic compounds which inhibit tyrosine kinases as described previously by Fraley et al (See USPN 6,306,874), and which further include inhibitors of the expression of EGF-R (i.e.

antisense), as well as including the compounds described more specifically in the instant specification, such as BIBX1522. Examples have been provided in the instant application for the ability of BIBX1522 to inhibit EGF-R in its ability to induce mucin expression in goblet cell proliferation.

The amount of direction or guidance presented in the specification AND the presence or absence of working examples. Applicants have not provided guidance in the specification toward a method of treating nasal polyps in an organism comprising the administration of any antagonist of EGF-R. The specification teaches the reduction in MUC5AC synthesis in goblet cells in vitro and in vivo comprising the administration of BIBX1522 prior to induction of goblet cell hyperplasia (and prior to EGF-R induction) via various means, including degranulation via inhalation of fMLP, exposure of cells or rats to cigarette smoke, IL13 induction, tracheal instillation of agarose plugs into rats, and administration of EGF or TNF-alpha. The specification fails to teach the successful delivery of any and/or all antagonists of EGF-R to an organism whereby treatment effects are provided for nasal polyps. One skilled in the art would not accept on its face the examples given in the specification of pretreatment with BIBX1522 (i.e. before goblet cell hyperplasia induction occurs in an organism) as being correlative or representative of the administration of any and/or all antagonists of EGF-R in an organism whereby treatment effects are provided for nasal polyps in view of the lack of guidance in the specification and known unpredictability associated with the administration and appropriate in vivo delivery of any and/or all EGF-R antagonists whereby treatment effects are provided in a subject. The specification as filed fails to

provide any particular guidance which resolves the known unpredictability in the art associated with in vivo delivery and treatment effects provided by the very broad genus comprising EGF-R antagonists.

The breadth of the claims and the quantity of experimentation required. The breadth of the claims is very broad. The claims are drawn to methods of treating nasal polyps comprising the administration of any epidermal growth factor receptor (EGF-R) antagonist to a patient suffering from nasal polyps. In order to practice the invention over the scope claimed, it would require undue trial and error and undue experimentation beyond which is taught in the specification to practice the invention drawn to any route of administration of any EGF-R antagonist to an organism such that treatment effects are provided for nasal polyps. The quantity of experimentation required to practice the invention as claimed would require the *de novo* determination of accessible target sites, modes of delivery and formulations to target appropriate cells and /or tissues harboring EGF-R such that any and/or all antagonists successfully inhibit EGF-R and further whereby treatment effects are provided in an organism for nasal polyps. Since the specification fails to provide any particular guidance for the successful delivery of such a broad array of compounds (i.e. encompassing any and/or all EGF-R antagonists) in an organism, and since determination of these factors for a particular inhibitor or antagonist of EGF-R is highly unpredictable, it would require undue experimentation to practice the invention over the scope claimed.

Conclusion

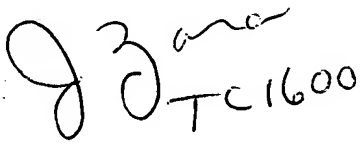
Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
3-2-07



JANE ZARA, PH.D.
PRIMARY EXAMINER